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IFW

Atty Docket No. 101982
(formerly ME03-009)
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of David M. Waisman — Art Unit 1635
Serial No. 10/735,577
Filed December 12, 2003
Confirmation No. 2576
For: COMPOSITIONS AND METHODS FOR INHIBITING TUMOR GROWTH AND METASTASIS
Examiner: Tracy A. Vivlemore

July 25, 2005

RESPONSE TO RESTRICTION REQUIREMENT

TO THE COMMISSIONER FOR PATENTS,

SIR:

This letter is in response to the Office action of June 24, 2005, which an election as between the following groups of claims for prosecution on the merits was requested: (1) Group I (claims 2-8, 17 and 18) directed to a composition that modulates activity of a p11 protein wherein the composition is an antisense p11 polynucleotide, (2) Group II (claims 2, 3, 9-13, 17, and 18) directed to a composition that modulates activity of a p11 protein wherein the composition is small interfering RNA specific to p11, (3) Group III (claims 2 and 14-18) directed to a composition that modulates activity of a p11 protein wherein the composition is a sense p11 polynucleotide, (4) Group IV (claims 19-36) directed to methods of modulating activity of p11 (5) Group V (claims 37-41) directed to a method of making a clonal cell, (6) Group VI (claim 42) directed to a clonal cell line produced by the method of claim 37, and (7) Group VII (claims 43 and 44) directed to a method of identifying a composition that modulates p11 activity.

According to 35 U.S.C. §121, a restriction is proper only if there are at least two independent and distinct inventions. Furthermore, "[i]f the search and examination of an

entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions."[1]

In this case, restriction is not proper. The claims of Group I, Group II, Group III, Group IV, Group V, Group VI, and Group VII each have a common element, **a protein involved in plasminogen activation**, i.e., p11. Any search of the prior art and examination involving Group I claims, therefore, will necessarily co-extend with the search and examination of Group II, Group III, Group IV, Group V, Group VI, and Group VII claims. Moreover, the prior art regarding proteins involved in plasminogen activation is sufficiently sparse to allow the examination of these claims without undue burden. Thus, as the examination of the entire application may be made without serious burden, the claims of Groups I, II, III, IV, V, VI, and VII should be examined together in accordance with MPEP §803.

In the alternative, and at the very least, the claims of Groups I and Group IV should be rejoined and examined together. In support of its restriction of Group I and Group IV, the Office states that the antisense polynucleotide of Group I and the method of Group IV are distinct because "the [antisense polynucleotide] product could be used in a materially different process."[2] While this assertion may be correct, it does not provide a proper basis for a restriction requirement. As detailed above, the claims of Group I are directed toward **a composition that modulates activity of a p11 protein wherein the composition is an antisense p11 polynucleotide** and the claims of Group IV are directed toward a method of modulating the activity of p11 (i.e., **by administering a composition comprising an antisense p11 polynucleotide**). No showing has been made that a search and examination of the prior art for an antisense p11 polynucleotide and a method of modulating the activity of p11 by administering to a cell an effective amount of an antisense p11 polynucleotide would be an undue burden. Without this showing, the Office has not established a prima facie case under 35 U.S.C §121. As such, the Applicant respectfully requests rejoinder of the Group I and Group IV claims.

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[1] MPEP §803 (emphasis added).
[2] See Office action at page 4.

The Applicant, subject to the foregoing traverse, hereby elects to prosecute the claims of Group I, claims 2-8, 17, and 18, drawn to a composition that modulates activity of a p11 protein wherein the composition is an antisense p11 polynucleotide.

The Office action also required restriction to a single nucleotide sequence, with regard to claims 5-7, 10-13, 20, 24, 29, and 34. Claims 5-7, 10-13, 20, 24, 29, and 34 each claim multiple SEQ ID NOs, which are targeted to and modulate the expression of p11. The Office action stated that "[a]lthough the nucleotide sequences claimed each target and modulate expression of p11, the instant sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct . . . ." Thus, according to the Office action, the Markush/genus of sequences in each of the above-mentioned claims "are not considered to constitute a proper genus, and are therefore subject to restriction."[3]

According to M.P.E.P. §803.02, a Markush-type claim can include independent and distinct inventions. In applications containing such claims, "the Examiner may require a **provisional election** of a single species prior to examination on the merits." Following election of a species, "the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability." Thus, if the Office finds no prior art that anticipates or renders obvious the elected species, it is incumbent upon the Office to search **additional species** in the Markush-type claim.

Applicant hereby elects to prosecute SEQ ID NO:16.

Applicant reserves the right to file divisional applications directed to the subject matter of the non-elected claims.

The Commissioner is authorized to charge any deficiency or credit any overpayment of fees in connection with this Response to Restriction Requirement to Deposit Account No. 50-1662.

Respectfully submitted,

[3] See Office action at page 12.

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): David M. Waisman			Matter No. # **101982** **(formerly ME03-009)**	
Serial No.	Filing Date	Examiner	Group Art Unit	Confirmation No.
10/735,577	December 12, 2003	Tracy A. Vivlemore	1635	2576

Invention: COMPOSITIONS AND METHODS FOR INHIBITING TUMOR GROWTH AND METASTASIS

I hereby certify that a Transmittal (2 pages, in duplicate); a Response to Restriction Requirement (4 pages); authorization to charge any fees which may be required, or credit any overpayment, to Deposit Account 50-1662; a Certificate of Mailing by Express Mail (1 page); and a stamped, pre-addressed postcard are being mailed by U.S. Postal Service Express Mail to Addressee: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, this 25th day of July, 2005.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	David M. Waisman	Group No.	1635
Serial No.:	10/735,577	Examiner:	Tracy A. Vivlemore
Filed:	December 12, 2003	Confirm. No.	2576
For:	COMPOSITIONS AND METHODS FOR INHIBITING TUMOR GROWTH AND METASTASIS		

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TRANSMITTAL

Dear Sir:

Attached please find the following:

- ☒ Response to Restriction Requirement (4 pages)
- ☒ Certificate of Mailing by Express Mail
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The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account No. 50-1662.

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I hereby certify that, on the date shown below, this correspondence is being

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M. Sue Clements	M. Sue Clements	7-25-05
Name of Depositor	Signature	Date

Respectfully submitted,

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Date: July 25, 2005

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